quinn emanuel trial lawyers | new york
51 Madison Avenue, 22nd Floor, New York, New York 10010-1601 | TEL (212) 849-7000 FAX (212) 849-7100

WRITER'S DIRECT DIAL NO.
(212) 849-7412

WRITER'S EMAIL ADDRESS
raynimrod@quinnemanuel.com

August 1, 2023

VIA ECF

Hon. Mary Kay Vyskocil
United States District Court
Southern District of New York
500 Pearl Street, Room 2230
New York, NY 10007

Re: *Acuitas Therapeutics Inc. v. Genevant Sciences GmbH et al.,*
Case No. 1:22-cv-02229-MKV

Dear Judge Vyskocil:

We write on behalf of Defendants Genevant Sciences GmbH and Arbutus Biopharma Corporation (collectively, "Defendants"), in advance of the August 9, 2023 status conference, to update the Court on the proceedings in *Arbutus Biopharma Corp. et al. v. Pfizer Inc. et al.*, No. 3:23-cv-01876-ZNQ (D.N.J.) (the "NJ Action"). In early April, the parties to this action submitted letters to the Court regarding the filing of the Complaint in the NJ Action. (DI 63, 69, & 70). On July 10, 2023, Pfizer Inc. and BioNTech SE (collectively, "Pfizer/BNT") filed their Answer and Counterclaims in the NJ Action (the "NJ Counterclaims"). The NJ Counterclaims, attached as Exhibit A, are relevant to this action in several respects.

First, the NJ Counterclaims undermine Acuitas's central argument in opposition to Defendants' pending motion to dismiss. The first sentence of Acuitas's opposition brief argues that subject matter jurisdiction exists here because its Amended Complaint purportedly falls into a long line of "declaratory judgment action[s] by a product supplier." (DI 50 at 1). But the NJ Counterclaims demonstrate that Acuitas is not a product supplier for Pfizer/BNT's vaccine, but instead simply a grantor of a ***license*** to intellectual property. Moreover, the license only covered ***two lipids*** rather than the entire LNP formulation included in the mRNA-LNP vaccine in question, much less the mRNA-LNP vaccine itself. (*See* Ex. A at 55). Those allegations regarding two lipids are impossible to square with Acuitas's Amended Complaint, which suggests that Acuitas actually *licenses and supplies* the *entire LNP* in the vaccine and perhaps also the *entire mRNA-LNP* that comprises the vaccine. (*See* DI 42 ¶ 5 ("Acuitas's mRNA-LNP is used, under license, in Pfizer and BioNTech's COVID-19 vaccine"); ¶ 16 ("Acuitas has partnered with non-parties BioNTech and Pfizer to supply and license the LNP used in COMIRNATY"); ¶ 22 (Acuitas "joins a long history of product suppliers" in filing suit)).

Second, the NJ Counterclaims undermine Acuitas's argument that it has an indemnity obligation to BioNTech that supports subject matter jurisdiction. As a threshold matter, the NJ Counterclaims do not allege or even suggest that Acuitas has such an indemnity obligation. More importantly, by confirming that Acuitas merely licensed two lipids, the NJ Counterclaims demonstrate that Acuitas has no indemnity obligation at all. That is because the indemnity agreement only covers liability based [redacted] (DI 50 at 5) and it is now clear that the limited amount of technology that Acuitas licensed—*i.e.,* the two lipids—could never be [redacted] Rather, BioNTech liability for infringement of the patents asserted in the NJ Action would require the manufacture, sale, or offer for sale of a *fully assembled RNA-LNP formulation* (complete with RNA and at least three lipids), as required by each of the asserted patents.

Third, the NJ Counterclaims support discretionary denial of jurisdiction. Pfizer/BNT—the direct infringers—not only consented to personal jurisdiction and venue in the NJ Action, they are also seeking to resolve counterclaims of non-infringement and invalidity in that venue. (*See* Ex. A at 8, 10, 49-73). Thus, the NJ Action is uniquely suited to resolve the entire controversy between Pfizer/BNT—the direct infringers—and Defendants with respect to infringement of the asserted patents. In contrast, a final judgment in favor of Defendants in this action would not be binding on Pfizer/BNT, requiring Defendants to re-litigate infringement and validity in New Jersey. Moreover, no matter what the outcome here, Defendants would still need to litigate the infringement and validity issues for U.S. Patent Nos. 11,298,320 and 11,318,098, which are at issue in the NJ Action, but not in this action. (Ex. A at 37-46).

Finally, Pfizer and BioNTech's decision to answer the Complaint and present their counterclaims in the NJ Action confirms that this Court should decide Defendants' pending motion to dismiss irrespective of the proceedings in New Jersey. Pfizer and BioNTech have not attempted to implead Acuitas in the NJ Action; they have not moved to dismiss on the basis that Acuitas is a necessary party; they have not alleged or pled facts showing that Acuitas indirectly infringed Defendants' patents or even supplied any component of the vaccine; and they have not alleged or pled that Acuitas has an indemnity obligation. The closest Pfizer and BioNTech have come to any of this is an affirmative defense that states, in its entirety, "Plaintiffs' Complaint improperly failed to name or join Acuitas Therapeutics, Inc." (Ex. A at 48). That assertion is unexplained, unsupported, and inconsistent with the fact that Defendants' patents in this action are directed to RNA-LNP formulations that Acuitas neither licenses nor supplies.

We appreciate the Court's time and attention and look forward to addressing these and related issues with the Court on August 9.

Respectfully submitted,

/s/ Raymond N. Nimrod

Raymond N. Nimrod

cc: All Counsel of Record (via ECF)